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PRODUCT NAME: Synergy Tabs

ACTIVE INGREDIENT: Disodium baborate pentahydrate (sodium tetraborate pentahydrate)

COMPANY NAME: Bio-Lab, Inc.

I.D. NUMBER: 166249-N

DOCUMENT NUMBER: none

EPA REGISTRATION NUMBER: 5185-435

TITLE: Review for Insignificant Human Exposure

Synergy Tabs contains two active ingredients: trichloro-s-triazinetriene (91.5%) and disodium baborate pentahydrate (5.0%). It is exclusively designed for use with Synergy System. This product is in the form of tablets, each weighing 14 grams. The tablets are for use in floaters and automatic type feeders to provide pool water sanitization. The label recommends using 11 tablets for each 10,000 gallons of pool water as the initial treatment and assuming half or more of the tablets will be remaining after 3 to 4 days. The refilling should occur every week.

The Registration Branch requested a review to determine if the use of this product according to the labeling would result in insignificant human exposure to disodium baborate pentahydrate. Except for the product labels, no data were provided with this submission. While there are two active ingredients in this product, this review of exposure is limited to disodium baborate pentahydrate (DBP) only.

Protective clothing and rubber gloves are required when handling this product, mainly because of its corrosiveness. The use of gloves and clothing during handling will also reduce dermal exposure to DBP. In addition, the dermal absorption of borates is very low (<1%) and no exposure via inhalation is anticipated because of the low vaporization property of borates and the physical form of this product (tablets). Therefore, exposure during handling is not much of concern when compared to the exposure during swimming. To estimate the exposure during swimming, a swimmer exposure assessment model that has been developed by the USEPA (Dang, 1997) was used. The model assumes an exposure time (ET) of 2.6 hours/day and an exposure frequency (EF) of 7 days/year as a higher end for an average swimmer in the U.S. An ET of 0.5 hour/event (one event/day), EF of 5 events/year, and water ingestion of 0.05 L/event were assumed as reasonable values for a non-competitive swimmer. For a competitive swimmer, an ET of 3 hours/event (one event/day), EF of 150 events/year, and water ingestion of 0.158 L/event were considered reasonable values. The routes of exposure that were considered in this model were oral, dermal, buccal/sublingual, orbital/nasal, aural, inhalation, and male sexual organ.

Because of the extremely low dermal absorption rate of borates and the small surface areas of some of these exposure sites, we considered oral and total dermal routes of exposure only to estimate the exposure to swimmers. Inhalation exposure was considered negligible because of the very low vaporization property of borates. DBP accumulation in pool water was calculated based on the use of 11 tablets (14 grams/tablet) in 10,000 gallons of pool water every week for two years with no significant removal through filtration. The final concentration after two years (20.8 mg/L or 0.021 mg/cm³ DBP or 3.1 mg/L boron equivalent) was used to calculate the exposure as follows:

DBP Dermal route of exposure:

T_{der} = Total dermal absorption (mg/day)

ET = Exposure time (hr/day)

SA = Body surface area (m²)

K_p = Permeability coefficient (cm/hr)

C_w = Concentration in water (mg/mL or mg/cm³)

$$T_{der} = ET \times SA \times 10^4 \times K_p \times C_w$$

Non-competitive Swimmer:

$$\text{Adult } T_{der} = 0.5 \text{ hr/day} \times 2.0 \text{ m}^2 \times 10^4 \times 0.001 \text{ cm/hr}^a \times 0.021 \text{ mg/cm}^3 = 0.21 \text{ mg/day}$$

$$\text{Child (six years old) } T_{der} = 0.5 \text{ hr/day} \times 0.83 \text{ m}^2 \times 10^4 \times 0.001 \text{ cm/hr}^a \times 0.021 \text{ mg/cm}^3 = 0.09 \text{ mg/day}$$

Competitive Swimmer:

$$\text{Adult } T_{der} = 3.0 \text{ hr/day} \times 2.0 \text{ m}^2 \times 10^4 \times 0.001 \text{ cm/hr}^a \times 0.021 \text{ mg/cm}^3 = 1.26 \text{ mg/day}$$

$$\text{Child (six years old) } T_{der} = 3.0 \text{ hr/day} \times 0.83 \text{ m}^2 \times 10^4 \times 0.001 \text{ cm/hr}^a \times 0.021 \text{ mg/cm}^3 = 0.52 \text{ mg/day}$$

a - Default permeability coefficient of 10⁻³ for inorganic compounds (US EPA, 1992).

DBP Oral route of exposure:

T_{oral} = Total oral absorption (mg/event)

CR = Contact rate (L/event)

C_w = Concentration in water (mg/L)

ET = Exposure time hr/event (one event/day)

$$T_{oral} = ET \times CR \times C_w$$

Non-competitive Swimmer:

$$\text{Adult } T_{oral} = 0.05 \text{ L/event (0.5 hr)} \times 20.8 \text{ mg/L} = 1.04 \text{ mg/day}$$

$$\text{Child (six years old) } T_{oral} = 0.05 \text{ L/event} \times 20.8 \text{ mg/L} = 1.04 \text{ mg/day}$$

Competitive Swimmer:

$$\text{Adult } T_{der} = 0.158 \text{ L/event (3 hr)} \times 20.8 \text{ mg/L} = 3.29 \text{ mg/day}$$

$$\text{Child (six years old) } T_{der} = 0.158 \text{ L/event (3 hours)} \times 20.8 \text{ mg/L} = 3.29 \text{ mg/day}$$

Table 1. DBP Total Exposure (mg/day)

Swimmers	Dermal exposure	Oral exposure	ADD ^a	ADD ^b
Non-competitive Adult	0.21	1.04	1.25	0.19
Non-competitive Child	0.09	1.04	1.13	0.17
Competitive Adult	1.26	3.29	4.55	0.69
Competitive Child	0.52	3.29	3.81	0.58

a - DBP absorbed daily dosage.

b - Boron equivalent absorbed daily dosage (corrected for boron/DBP ratio of 44/291).

A default permeability coefficient of 10^{-3} cm/hour was used to estimate dermal absorption. This is a conservative assumption for borates which may have a permeability of much less than 10^{-3} . This conservative assumption would result in conservative estimate of dermally absorbed doses. Studies have shown no or insignificant absorption of boric acid from intact skin (Draize and Kelley, 1958; Stuttgart, *et al.*, 1982; Pfeiffer, *et al.*, 1945), but it is readily absorbed from broken or abraded skin (Stuttgart, *et al.*, 1982; Pfeiffer, *et al.*, 1945).

Boron is present in food, water, laundry and hand soaps, cosmetics, and pharmaceuticals. The daily intake of boron from water and food has been estimated to range between 0.5 to 20 mg/day for an adult human, with an average of 3 mg/day (Hunt, *et al.*, 1991; Seiler and Sigel, 1988; WHO, 1973; Nielsen, 1991). A typical school lunch provides approximately 0.5 mg of boron (WHO, 1973). California does not have a standard for boron in drinking water. Seiler and Sigel, 1988 reported a tolerance level of 1 mg/L for boron in drinking water that was set by the U.S. Department of Interior (USDI). The final concentration of boron in a pool after two years, based on the assumption of weekly use of Synergy Tab, will be 3.1 mg/L (boron equivalent) or approximately three fold of its tolerance in drinking water. Considering the actual use and use reduction during winter months, the actual concentration after two years could be much less and closer to boron tolerance in drinking water. In addition, the estimates of boron ADD in Table 1 for competitive and non-competitive swimmers are based on the exposure after two years of application. The exposure during the length of this period would be much less. The estimates of ADD in Table 1 are considerably below the average human daily boron intake from food and water.

Recommendation:

Based on the submitted data, human exposure to DBP from the use of Synergy Tabs in pool water is insignificant.

References:

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